UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

KOLEEN OTIS-WISHER,	:	
	:	
Plaintiff,	:	
	:	
v.	:	File No. 1:11-cv-64-jgm
	:	
FLETCHER ALLEN HEALTH CARE, INC., MEDTRONIC, INC. and MEDTRONIC SOFAMAR DANEK USA, INC.,	:	
	:	
Defendants.	:	
	:	

RULING ON MEDTRONIC DEFENDANTS' MOTION TO DISMISS
(Docs. 55, 58)

I. Introduction

In this diversity action commenced in March 2011, Plaintiff Koleen Otis-Wisher ("Otis-Wisher" or "Plaintiff") asserts a variety of common-law tort and consumer fraud claims against Defendants Fletcher Allen Health Care, Inc. ("Fletcher Allen"), Medtronic, Inc. and Medtronic Sofamar Danek USA, Inc. ("Medtronic"). (Doc. 35 ("Compl.").) The claims arise from Otis-Wisher's spinal surgery at Fletcher Allen on March 27, 2008. She initially filed suit against Fletcher Allen alleging only medical malpractice. (Doc. 1.) In an amended complaint dated February 2012, she added claims for lack of informed consent and consumer fraud against Fletcher Allen and brought claims against Medtronic. (Doc. 35.) Specifically, Otis-Wisher brings claims against Medtronic for fraudulent misrepresentation and inducement, constructive fraud, strict products liability failure to warn, manufacturing and design defect, negligence, negligent misrepresentation, and consumer fraud. Medtronic moves to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). (Doc. 55) Fletcher Allen also moves to dismiss the lack of informed consent and consumer fraud claims as time-barred. (Doc. 58.) Otis-Wisher opposes the motions. (Docs. 63, 71.) Having considered the parties' pre-hearing memoranda, arguments made at the

June 4, 2013 hearing, and post-hearing memoranda (Docs. 85, 87-88), for the following reasons, Medtronic's motion is granted and Fletcher Allen's motion is granted in part and denied in part.

II. Background

For purposes of ruling on this motion to dismiss, the Court accepts as true all well-pleaded allegations in the amended complaint, as summarized below.

In April 2007, Plaintiff Koleen Otis-Wisher was involved in a car accident, sustaining various injuries, including a C2 fracture. On March 27, 2008, after unsuccessful conservative treatment, she underwent a posterior C1-2 fusion at Fletcher Allen Hospital. The surgery included the use of the Medtronic product Infuse to augment fusion. Plaintiff alleges the use of Infuse posteriorly was an "off-label" use which was not approved by the FDA, she was not adequately informed of the risks or potential side effects of Infuse, and was not informed her doctor had a financial and development relationship with Medtronic "such that he actively promoted the use of that company's products." Compl. ¶ 17.

After conducting its premarket approval (PMA) review,[1] on July 2, 2002, the FDA approved Medtronic's Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse"), a Class III device, as safe and effective for its intended use. See Doc. 55-1 at 5 (pointing the Court to publicly available documents as evidence of Infuse's FDA approval). Each change or modification to Infuse -- 37 total -- has undergone a supplemental PMA process. Id. Infuse, an implantable device used to help fuse the spine, is comprised of three components: a genetically engineered protein (rhBMP) capable of initiating bone growth; an absorbable collagen sponge; and a titanium cage. See Compl. ¶ 72; Doc. 55-1 at 1 n.1. The "intended use" of the device is spinal fusion procedures in skeletally

[1] For a more detailed discussion of the PMA process, see Section III.B. below.

mature patients with degenerative disc disease at one level from L4 to S1 and is to be implanted through an anterior open or anterior laparoscopic approach.

Ms. Otis-Wisher had immediate relief of discomfort for two days following the surgery but her pain gradually increased. She was prescribed pain medication, muscle relaxants and physical therapy. She experienced neck pain and spasm, pain and numbness in her left arm, trouble sleeping and occasionally swallowing liquids, and hoarseness. Her neck range of motion was very limited laterally and was flexed forward into a swan neck deformity. In June 2009, she saw a spinal surgeon at Massachusetts General Hospital (MGH) who determined she had a "robust fusion mass about her posterior cervical spine extending from the occiput to C3 that had fused in a kyphotic position." Compl. ¶ 50. To alleviate her chronic muscle strain and improve her swallowing ability, Ms. Otis-Wisher underwent a two-stage surgery in October 2009. On October 1, Dr. Wood of MGH performed an anterior cervical discectomy. On October 5, he performed a posterior spine fusion. The surgeries revealed exuberant bone growth in Ms. Otis-Wisher's cervical spine that she alleges was caused by the off-label use of Infuse. She continues to suffer neck pain and spasms, limited neck range of motion, excess bone growth, voice issues and difficulty swallowing.

Ms. Otis-Wisher alleges the use of Infuse posteriorly in her cervical spine surgery was not approved by the FDA, i.e., an "off label" use; Physicians may use FDA approved medical devices for off-label uses with a patient's informed consent. She alleges Medtronic promoted and sold Infuse to be used off label though it was "not permitted to promote off label use or to provide doctors inducements to promote off label uses." Compl. ¶ 74. Use of Infuse in a cervical spine surgery can cause ectopic or exuberant bone growth on or around the spinal cord which can compress nerves and cause side effects such as intractable pain, spasms, difficulty swallowing, and voice issues. Ms. Otis-Wisher alleges Medtronic represented Infuse was a safe and effective device

for spinal fusion surgery but that it knew Infuse was not safe for off-label use and failed to alert her of the extreme danger to patients of off-label use.

III. Discussion

A. Legal Standard

A motion to dismiss tests the legal rather than the factual sufficiency of a complaint. See, e.g., Sims v. Ortiz, 230 F.3d 14, 20 (2d Cir. 2000). The Court will grant a motion to dismiss only if the pleader fails to show a "plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). The Court accepts the facts alleged in the pleading as true, draws all reasonable inferences in favor of the pleader, and dismisses only "if the facts as alleged are insufficient to raise a right to relief above the speculative level." Price v. N.Y. State Bd. of Elections, 540 F.3d 101, 107 (2d Cir. 2008) (citation and internal quotation marks omitted). A complaint must state a plausible -- not just possible -- claim for relief to survive a motion to dismiss. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). Determining whether a complaint survives a motion to dismiss requires the court to make a "context-specific" analysis and "draw on its judicial experience and common sense." Id. at 1950 (internal citations omitted).

B. Medtronic's Motion to Dismiss

1. The Medical Device Amendments

The Medical Device Amendments (MDA) to the Federal Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., imposed detailed federal oversight for medical devices and swept back state oversight schemes. Riegel v. Medtronic, Inc., 552 U.S. 312, 312 (2008). New Class III devices, such as Medtronic's Infuse Bone Graft, receive the most intense federal oversight and are subject to a "rigorous" premarket approval process. Id. at 317; see also 21 U.S.C. § 360c(a)(1)(C)(ii).

The FDA spends an average of 1,200 hours reviewing an application and grants premarket approval only if it finds reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360e(d). The PMA process includes review of the device's proposed labeling, id. § 360e(d)(1)(A), and a grant of PMA may include restrictions upon the sale or distribution of the device or compliance with other requirements, 21 C.F.R. § 814.82.

After approval, the MDA forbids the manufacturer from making any changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness without FDA permission. 21 U.S.C. § 360e(d)(6)(A)(1). To make such a change, the manufacturer must receive FDA approval of an application for supplemental premarket approval. Id. § 360e(d)(6).

The MDA also imposes post-approval reporting requirements on the medical device manufacturer. 21 U.S.C. § 360i. These include obligations to inform the FDA of new clinical investigations or scientific studies concerning the device, which the manufacturer knows or reasonably should know of, 21 C.F.R. § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, id. § 803.50(a).

Finally, the FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines a device is unsafe or ineffective under the conditions in its labeling. 21 U.S.C. § 360e(e)(1), § 360h(e). It can also order a labeling change based on newly acquired information. Id. § 360f(a)(2).

2.. MDA Preemption Clause

The MDA contains an explicit preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption. Id. § 360k(b). Plaintiff does not allege any relevant subsection (b) exception applies in this action.

The Supreme Court has interpreted the preemption clause in the MDA as preempting state law claims when (1) the federal government has established specific requirements applicable to the device, and (2) the state law claims are based on requirements that are "different from, or in addition to the federal ones" and relate to the safety and effectiveness of the device. Riegel, 552 U.S. at 321-23. Because premarket approval is specific to a device and is entirely concerned with the safety and effectiveness of that device, PMA imposes "specific requirements" that can preempt state common law duties. Id. Accordingly, the question, as it was in Riegel, is whether Otis-Wisher's common law claims rely on "'any requirement'" of Vermont law applicable to the Medtronic device that is "'different from, or in addition to'" federal requirements and that "'relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" Id. at 323 (quoting 21 U.S.C. § 360k(a)). If so, the claim is preempted by the MDA. As in Riegel, "safety and effectiveness are the very subjects" of Plaintiff's common law claims here so the "critical issue" is whether Vermont's tort duties constitute "requirements" under the MDA. Id. The Riegel Court held common-law duties do constitute "requirements," such that common-law causes

of action for negligence and strict liability impose requirements and are preempted by the federal requirements specific to a medical device. Id. at 323-24.

A state law claim may survive, however, if the claim relies on a state requirement that "parallels" the federal requirement. A State may provide a damages remedy for a claim premised on the violation of FDA regulations. Riegel, 552 U.S. at 330. The state regulation is said to parallel rather than add to or differ from federal requirements. Id. To "successfully thread the needle," -- and comply with Twombly -- a plaintiff must do more than "simply incant the magic words 'Medtronic violated FDA regulations' in order to avoid preemption." In re Medtronic, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009). A plaintiff must allege in detail the federal requirement allegedly violated and also allege a cognizable link between the violation(s) and the injury suffered. Gelber v. Stryker Corp., 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010).

Claims almost identical to those raised here -- also concerning alleged off-label promotion and posterior use of Infuse -- were recently rejected as preempted. Caplinger v. Medtronic, Inc., -- F. Supp. 2d --, No. Civ-12-630, 2013 WL 453133 (W.D. Okla. Feb. 6, 2013). The district court diligently analyzed each common law claim in a thorough ruling detailing the statutory and regulatory framework, the PMA process, and preemption. The Caplinger court found "that regardless of plaintiff's off-label promotion allegations, each of plaintiff's claims must be analyzed to determine whether it is preempted." Id. at *10. The court determined claims of fraudulent misrepresentation, fraud in the inducement, constructive fraud, strict products liability-failure to warn, strict products liability-design defect, breach of express and implied warranty, negligence, and negligent misrepresentation were each preempted and must be dismissed. See generally id.

The Court is aware of state court decisions which have refused to dismiss products liability claims stemming from off-label use and promotion. See Cornett v. Johnson & Johnson, 998 A.2d

543 (N.J. Super. 2010); Huggins v. Medtronic, Inc., No. 12CV40, slip op. (Colo. D. Ct. Feb. 21, 2013). The Cornett court acknowledged parallel claims because deviation from FDA approved design and manufacturing requirements as well as off-label marketing in violation of federal law was alleged. The Huggins decision is two pages and does not contain analysis but holds the "claims against Medtronic are not . . . preempted by federal law as they are premised on conduct that allegedly violates 'applicable FDCA and FDA regulations' and thus parallels federal requirements." Huggins, slip op. at *2. Notwithstanding these decisions, this Court finds the Caplinger decision particularly instructive.

Here, none of Otis-Wisher's common-law claims allege any specific federal requirement. In Count VIII, her negligence claim, Ms. Otis-Wisher makes three allegations she claims as bases for Medtronic's liability, including: "Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse." Compl. ¶ 151. Because this allegation does not state a device specific violation of federal law, it is not sufficient to avoid preemption.

None of the other common law claims even include a reference to federal law. For example, Count V, a strict products liability failure to warn claim alleges the "warnings accompanying the Infuse product" did not adequately warn of the dangers and failed to provide information an ordinary user would expect. Compl. ¶¶ 123-24. Without an allegation that the accompanying warnings were other than those approved and mandated by the FDA, the claim must fail. It cannot state a "parallel" claim without stating a violation of federal law. Additionally, to the extent Plaintiff's failure to warn claim is based on FDA-approved labeling, it is barred.[2]

[2] As noted above, once a device receives premarket approval, the MDA forbids the manufacturer to make changes to labeling that would affect safety or effectiveness without FDA permission. 21 U.S.C. § 360e(d)(6)(A)(1).

Counts VI and VII, strict products liability claims for manufacturing defect and design defect, are also insufficient. Count VI does not allege any federal requirement with which Medtronic failed to comply in manufacturing Infuse. See Compl. ¶¶ 128-36. Count VII does not allege the design of Infuse was anything other than the design approved by the FDA. See Compl. ¶¶ 137-43. To award premarket approval to Infuse, the FDA necessarily found reasonable assurance of the device's safety and effectiveness. Again, Plaintiff cannot state a parallel claim without stating a violation of federal law.

Lastly, Plaintiff alleges claims of fraud and misrepresentation. Count III alleges fraudulent misrepresentation and inducement, Count IV alleges constructive fraud, and Count IX alleges negligent misrepresentation. The alleged misrepresentations and omissions are: "sponsoring biased medical trials, reports, and articles that concluded that the dangers inherent to off label use of Infuse did not exist or were significantly less tha[n] the actual dangers," Compl. ¶ 157; concealing "the health and safety hazards, symptoms, diseases and/or health problems associated with the off label cervical use of [] Infuse," id. ¶ 105(a); "promoti[ng] and marketing to physicians . . . the off-label use of Infuse in cervical spine surgery," id. ¶ 105(b); and, "concealing "information about the known comparative risks and benefits of the use of Infuse and the relative benefits and availability of alternate products, treatments and/or therapies," id. ¶ 105(c). Ms. Otis-Wisher does not aver any of these alleged misrepresentations or omissions were in violation of any specific federal law.[3]

[3] The Complaint contains a statement in the "factual background relating to Medtronic Defendants" section that "Medtronic Defendants are not permitted to promote off label use or to provide doctors inducements to promote off label uses." Compl. ¶ 74. This is not a sufficiently specific allegation of the federal requirement allegedly violated. Medtronic also points to a recent Second Circuit decision that noted: "While the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion." United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012). Ms. Otis-Wisher makes no allegations of misbranding.

Because Otis-Wisher has failed to plead her misrepresentation and fraud claims with the particularity required by Federal Rule of Civil Procedure 9(b), they would be dismissed even if they adequately alleged a violation of federal law. Rule 9(b) requires parties to allege "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).[4] Pleading with particularity means the complaint must "detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 187 (2d Cir. 2004) (citation omitted). Plaintiff here has not alleged any particular statements or speaker(s) let alone when and where any such statements were made. Bare bones allegations do not satisfy Rule 9(b).

Despite submitting a twenty-five page opposition to Medtronic's motion to dismiss, Plaintiff does not once cite to her complaint. See Doc. 71. For the reasons set forth above, Plaintiff's common law claims against Medtronic are dismissed. Accordingly, the Court need not consider Medtronic's remaining arguments concerning the statute of limitations and superseding cause.

3. Consumer Fraud Claim

Medtronic also moves to dismiss Plaintiff's consumer fraud claim. (Doc. 55-1 at 25.) The Vermont Consumer Fraud Act defines consumer as "any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale . . . but for his or her use or benefit or the use or benefit of a member of his or her household . . . ." Vt. Stat. Ann. tit. 9, § 2451a(a). Medtronic argues Otis-Wisher does not fit this definition because Infuse, a prescription medical device, is not purchased for personal use, but is instead prescribed by a doctor

[4] While this is a diversity case in which federal procedural rules apply, the Court notes the Vermont Rules of Civil Procedure also require fraud be pled with particularity. Vt. R. Civ. P. 9(b).

and installed in a patient. Plaintiff responds by referring to her opposition to Fletcher Allen's motion to dismiss, but it is not responsive to Medtronic's argument regarding the definition of consumer. See Doc. 63 at 11-14; Doc. 71 at 24. Because Plaintiff does not fit the definition of consumer, the Court finds she has not stated a claim for violation of the Vermont Consumer Fraud Act against Medtronic.

C. Fletcher Allen's Motion to Dismiss

Fletcher Allen moves to dismiss Counts II and X, the lack of informed consent and consumer fraud claims, under Rule 12(b)(6) arguing both are time-barred and the consumer fraud claim is not actionable. (Doc. 58.) Plaintiff originally filed this action in March 2011 alleging medical malpractice against Fletcher Allen. (Doc. 1.) She then moved to amend her complaint to add Counts II and X in January 2012 and filed the amended complaint, following court approval, in February. The lack of informed consent claim alleges both that her doctor failed to inform her of the risks, benefits, alternatives and off-label use of Infuse/BMP in her surgery and the financial and developmental relationship between her doctor and Medtronic. Compl. ¶¶ 99-100. Ms. Otis-Wisher argues her claims are timely as they were filed within the relevant statute of limitation period following her discovery of the claims and, in any event, the claims "relate back" to the filing of the original complaint. (Doc. 63.) She also argues the consumer fraud claim is actionable because it stems from the entrepreneurial and financial practice of medicine. Id. at 11-14.

1. Lack of Informed Consent

A statute of limitations creates an affirmative defense when a plaintiff fails to bring suit within a specified period of time after the cause of action accrued and is often subject to tolling principles. Ma v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 597 F.3d 84, 88 n.4 (2d Cir. 2010). Vermont law requires "actions to recover damages for injuries to the person arising out of any

medical or surgical treatment or operation shall be brought within three years of the date of the incident or two years from the date the injury is or reasonably should have been discovered." Vt. Stat. Ann. tit. 12, § 521.

A late-filed claim may also be considered timely if it "relates back" to the date of the original timely pleading. Federal Rule of Civil Procedure 15(c)(1) provides:

> An amendment to a pleading relates back to the date of the original pleading when: (A) the law that provides the applicable statute of limitations allows relation back; (B) the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out–or attempted to be set out–in the original pleading; or (C) the amendment changes the party or the naming of the party against whom a claim is asserted . . . .

Fed. R. Civ. P. 15(c)(1). Rule 15(c) applies in federal courts. Ingram v. Kumar, 585 F.2d 566, 570 n.1 (2d Cir. 1978). Under the Rule, "the central inquiry is whether adequate notice of the matters raised in the amended pleading has been given to the opposing party within the statute of limitations by the general fact situation alleged in the original pleading." Stevelman v. Alias Research Inc., 174 F.3d 79, 86 (2d Cir. 1999) (internal quotation marks and citation omitted); see also 123 Main Street Assocs. v. Manko, 897 F. Supp. 1507, 1521 (S.D.N.Y. 1993) ("late filed claims properly relate-back to timely filed claims as long as the amendment does not produce an unfair surprise to the defendant"). Fletcher Allen acknowledges courts considering this precise issue regarding relation back of a lack of informed consent claim to a medical malpractice claim are split and the Second Circuit has not considered the issue. (Doc. 58 at 7.)

Plaintiff's lack of informed consent claim regarding her doctor's failure to inform her of the risks, benefits, alternatives and off-label use of BMP in her surgery clearly relates to the medical malpractice claim, and the underlying facts and set of circumstances are sufficiently set out in the original complaint. In her original complaint, she alleged a "surgical consent was signed to include the potential use of Bone Morphogenetic Protein ('BMP') posteriorly." (Doc. 1 ¶ 10.) Fletcher

Allen has had ample notice it must defend with respect to Plaintiff's surgery and could foresee a lack of informed consent claim might be brought against it. Further, Fletcher Allen has not shown it will be unduly prejudiced with the addition of this lack of informed consent claim. Accordingly, Ms. Otis-Wisher's lack of informed consent claim regarding the off-label use of Infuse relates back to the originally filed complaint and is timely.[5]

Plaintiff's lack of informed consent claim regarding the financial and developmental relationship between her doctor and Medtronic, however, is a different question. Vermont law defines lack of informed consent as the failure "to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved" in the professional treatment. Vt. Stat. Ann. tit 12, § 1909(a)(1); see also Christman v. Davis, 889 A.2d 746, 749 (Vt. 2005) ("If the patient . . . received inadequate disclosures of the alternatives and foreseeable risks and benefits of the alternatives, liability must be based on lack of informed consent."). Plaintiff's claim regarding the relationship between her doctor and Medtronic fails to state a viable claim for lack of informed consent because it does not concern alternatives, risks or benefits of the treatment. Consequently, it is dismissed under Rule 12(b)(6). The Court notes that the alleged relationship may be relevant in connection with the lack of informed consent claim regarding off-label use of Infuse.

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[5] The Court notes a claim may be dismissed on the basis of an affirmative defense under Rule 12(b)(6) only if "the facts supporting the defense appear on the face of the complaint," and "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief." McKenna v. Wright, 386 F.3d 432, 436 (2d Cir. 2004) (internal quotation marks and citation omitted). At this stage, Otis-Wisher is entitled to all reasonable inferences from the facts alleged, including those that defeat the statute of limitations defense. If the Court had not determined her claim relates back to the original complaint, it would not decide the discovery rule issue because "'the determination of when a plaintiff actually discovered or reasonably should have discovered his injury is a factual determination for the jury.'" Estate of Hitchcock v. Tonino, No. 1:05-cv-214, 2006 WL 2709684, at *5 (D. Vt. 2006) (quoting Ware v. Gifford Mem'l Hosp., 664 F. Supp. 169, 171 (D. Vt. 1987)).

2. Consumer Fraud Claim

Fletcher Allen moves to dismiss Plaintiff's consumer fraud claim arguing it is not actionable under Vermont law. (Doc. 58 at 10.) Otis-Wisher argues the consumer fraud claim is actionable because it stems from the entrepreneurial and financial practice of medicine. (Doc. 63 at 11-14.) She alleges Fletcher Allen committed deceptive acts or practices by materially misleading her about the safety and efficacy of Infuse and failing to disclose information material to a knowing consent. Compl. ¶ 165.

The Vermont Consumer Fraud Act (CFA) prohibits "[u]nfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce." Vt. Stat. Ann. tit. 9, § 2453(a). The purpose of the CFA is "to protect the public from unfair and deceptive business practices and to encourage fair and honest competition." Bisson v. Ward, 628 A.2d 1256, 1260 (Vt. 1993); Vt. Stat. Ann. tit. 9, § 2451. The CFA provides a private right of action to consumers who contract for goods or services in reliance upon false or fraudulent representations or practices prohibited by section 2453, or who sustain damages or injury as a result of the same. Vt. Stat. Ann. tit. 9, § 2461(b). The standard in Vermont for determining whether an act or practice is deceptive is: (1) a representation, practice, or omission likely to mislead; (2) that the consumer interprets reasonably under the circumstances; and (3) with "material" misleading effects, i.e., likely to affect consumers' conduct or decision with regard to a product. Bridge v. Corning Life Sciences, Inc., 997 F. Supp. 551, 553 (D. Vt. 1998) (citing Poulin v. Ford Motor Co., 513 A.2d 1168, 1171-72 (Vt. 1986)). Misrepresentations involving facts are actionable while those involving opinions are not. Id. (citation omitted). The Vermont Supreme Court has stated: "A plaintiff cannot simply recast a malpractice claim as a consumer fraud claim. . . . [W]e see no meaningful distinction

between lawyers and other professionals hired to give a 'specialized or expert interpretation' of a matter." Webb v. Leclair, 933 A.2d 177, 183 (Vt. 2007).

Here, Plaintiff's CFA claim against Fletcher Allen essentially parallels her lack of informed consent claim. As the Vermont Supreme Court has noted, the CFA was not meant to provide a second method to plead a malpractice or negligence claim. The Court finds Plaintiff has not stated a claim for violation of the Vermont Consumer Fraud Act against Fletcher Allen based on Dr. Braun's recommended course of treatment or alleged failure to provide full disclosure regarding Infuse. Accordingly, Plaintiffs' consumer fraud claim is dismissed.

V. Conclusion

For the reasons stated, the Medtronic defendants' motion to dismiss (Doc. 55) is granted. Counts III through IX of Plaintiff's Amended Complaint are DISMISSED. Fletcher Allen's motion to dismiss (Doc. 58) is granted in part and denied in part. Ms. Otis-Wisher's lack of informed consent claim regarding the off-label use of Infuse (Count II) relates back to the originally filed complaint and is timely. Her lack of informed consent claim regarding the relationship between her doctor and Medtronic (Count II) fails to state a claim and is DISMISSED. Plaintiff's consumer fraud claim (Count X) is DISMISSED as to all defendants for failure to state a claim.

SO ORDERED.

Dated at Brattleboro, in the District of Vermont, this 25th day of June, 2013.

/s/ J. Garvan Murtha
Honorable J. Garvan Murtha
United States District Judge